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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/832,365 | 04/10/2001 | Avram Scheiner | 279.280US1 | 7716 |

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| EXAMINER | |
|---|---|
| OROPEZA, FRANCES P | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3762 | 19 |

DATE MAILED: 03/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/832,365 | SCHEINER ET AL. | |
| | Examiner | Art Unit | |
| | Frances P. Oropeza | 3762 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *1/20/04 (Amendment and RCE)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *2-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *18*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Request for Continued Examination*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. The Applicant's submission filed on 1/20/04 has been entered.

### *Response to Amendment*

2. The Applicant's argument filed 1/20/04 are convincing hence the rejections of record have been withdrawn and a new rejection established in the subsequent paragraphs.

### *Claim Rejections - 35 USC § 102*

3. Claims 2-8, 15-25 and 28-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Hudrlik (US 5282840). Hudrlik discloses an implanted cardiac stimulation device comprising an impedance measuring system that defines a baseline impedance signal and detects a fluid shift away from the thorax (creating ischemia of the tissue). The device provides stimulation treatment to assist in shifting fluid back toward the tissue in the thorax (col. 2 @ 32-39). The impedance signal is attenuated by high and low filtering depending on the parameter monitored (respiration/activity/motion or fluid flow) and the pacing rate varied in dependence on the impedance measurements (abstract; col. 2 @ 8-16; col. 2 @ 53 – col. 3 @ 27; col. 3 @ 61-68; col. 4 @ 45-57; col. 6 @ 27 – 65; col. 7 @ 5-15; col. 9 @ 42-46; col. 10 @ 51 – col. 11 @ 54).

*Claim Rejections - 35 USC § 103*

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 9-12, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hudrlik (US 5282840) in view of Combs et al. (US 5957861). As discussed in paragraph 3 of this action, Hurdlik discloses the claimed invention except for the cutoff frequency for the fluid impedance signal being 0.01 to 0.5 Hz, or approximately 0.1 Hz.

Combs et al. teach measure the impedance of fluid using a measurement frequency range of 0.01 to 0.5 Hz, or approximately 0.1 Hz for the purpose of removing cardiac and respiratory components from the impedance signal. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used an impedance measurement frequency range of 0.01 to 0.5 Hz, or approximately 0.1 Hz in the Hurdlik system in order to avoid extraneous

noise in the fluid impedance signal so an accurate determination of the fluid level can be determined (col. 6 @ 58 – col. 7 @ 33).

6. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheldon et al. (US 6044297) in view of Pitts Crick et al. (US 6104949) and further in view of Hudrlik (US 5282840).

Sheldon et al. disclose an implantable stimulation device and teach hypotension detection, both postural (col. 7 @ 28) and non-postural (col. 7 @ 44), using activity sensors and heart rate sensors for the purpose of providing treatment to prevent the patient from fainting or feeling faint (col. 5@ 42-46; col. 6 @ 53-65; col. 7 @ 27-59; col. 9 @ 10-13). Sheldon et al. teach inclusion of blood pressure monitoring, read as monitoring of hypotension, to treat syncopal patients (col. 9 @ 10-13; col. 12 @ 10-31; col. 22 @ 4-9).

Sheldon et al. disclose the claimed invention except for using transthoracic impedance to indicate hypotension.

Postural hypotension (fluid moving to the patient's extremities and the patient being unable to compensate for this movement) and pulmonary edema (lungs filling with fluid and the patient being unable to compensate for this fluid collection) are recognized as conditions frequently associated with the later stages heart failure (Sheldon et al. – col. 7 @ 31-46; Pitts Crick et al. – col. 4 @ 48 – col. 5 @ 55; col. 5 @ 37-39; col. 6 @ 20-30). Both these conditions create changes in the fluid levels in the thoracic tissues as fluid is shifted away from the thorax in the hypotension condition and as fluid is shifted into the throrax in the edema

condition, hence accurate monitoring of fluid changes in the trans-thoracic tissues can quantify changes associated with the conditions of hypotension and pulmonary edema and can indicate the need for treatment (Sheldon et al. – col. 7 @ 31-46; col. 21 @ 62 – col. 22 @ 9; Pitts Crick et al. – abstract; col. 1 @ 38-45; col. 2 @ 35-40; col. 5 @ 34-39; col. 6 @ 20-30). Pitts Creek et al. teach the monitoring of fluid changes using the sensing of trans-thoracic impedance for the purpose of accurately monitoring the fluid level in the tissues, and correlating posture changes with impedance to diagnose and treat congestive heart failure.

The Applicant states treatment of hypotension can be based on trans-thoracic impedance and one or more secondary variables such as an accelerator to detect posture changes (specification – page 10, lines 15-19), hence absent any teaching of criticality or unexpected results, merely changing the basis for treatment of hypotension from an impedance sensor to an impedance and activity sensors would have been an obvious design choice.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have used trans-thoracic impedance sensors with posture sensors to monitor fluid changes in the Sheldon et al. system in order to utilize a proven means to measure shifts in thoracic fluids so automatic treatment is provided that rapidly responds to the early signs of fluid shifts in the thorax (col. 1 @ 40-46; col. 5 @ 34-39; col. 6 @ 20-30).

Modified Sheldon et al. disclose the claimed invention except the therapy shifting the fluid back to the thorax.

Hudrlik discloses an implantable stimulation device to manage fluid flow and teaches that gross tissue insults, created by a significant reduction of blood flow to tissue of the thorax, cause

Hudrlik discloses an implantable stimulation device to manage fluid flow and teaches that gross tissue insults, created by a significant reduction of blood flow to tissue of the thorax, cause dramatic shifts in the impedance (col. 2 @ 32-35). These fluid shifts are treated by increased pacing rates (col. 11 @ 30-43) for the purpose of assisting in shifting the fluid back to the thorax (col. 2 @ 32-29). Hudrlik teaches impedance and activity monitors are used to define the pacing treatment in situations of fluid shifts (col. 3 @ 9-15). As discussed previously, hypotension is recognized as being associated with a fluid shift to the extremities causing fainting or the feeling of being faint. The fluid shift associated with hypotension is read a significant reduction of blood flow in the thorax. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used thoracic impedance and activity sensors to monitor fluid shifts and to increase the pacing rate as needed to shift fluid back to the thorax in the modified Sheldon et al. system in order to utilize proven monitoring and treatment system for fluid shifts so adequate fluid flow is provided to the thoracic tissue avoiding tissue damage (ischemia) and preventing patient injury from falls that might result if the patient faints (col. 2 @ 32-39).

7. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheldon et al. (US 6044297) in view of Fefek-Petric et al. (US 5913879) and further in view of Standberg 0 620 420 A1) and further in view of Hudrlik (US 5282840).

Sheldon et al. disclose an implantable stimulation device and teach hypotension detection, both postural (col. 7 @ 28) and non-postural (col. 7 @ 44), using activity sensors and heart rate sensors for the purpose of providing treatment to prevent the patient from fainting or

feeling faint (col. 5@ 42-46; col. 6 @ 53-65; col. 7 @ 27-59; col. 9 @ 10-13). Sheldon et al. teach inclusion of blood pressure monitoring, read as monitoring of hypotension, to treat syncopal patients (col. 9 @ 10-13; col. 12 @ 10-31; col. 22 @ 4-9).

Sheldon et al. disclose the claimed invention except for using transthoracic impedance to indicate hypotension.

Ferek-Petric et al. disclose a implantable therapy device and teach detecting venous pooling (correlative to hypotension), read as detecting fluid shift away from the thorax, using a flow detector for the purpose of providing proper therapy (abstract; figure 2; col. 1 @ 7-11; col. 3 @ 17-63). Ferek-Petric et al. teach blood flow measurement can be made by impedance measurements (col. 2 @ 51-55) as taught by Strandberg using electrodes (col. 5 @ 11 – col. 6 @ 4).

The Applicant states treatment of hypotension can be based on trans-thoracic impedance and one or more secondary variables such as an accelerator to detect posture changes (specification – page 10, lines 15-19), hence absent any teaching of criticality or unexpected results, merely changing the basis for treatment of hypotension from an impedance sensor to an impedance and activity sensors would have been an obvious design choice.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have used trans-thoracic impedance sensors with posture sensors to monitor fluid changes in the Sheldon et al. system in order to utilize a proven means to measure shifts in thoracic fluids so automatic treatment is provided that rapidly responds to the early signs of fluid shifts in the thorax (col. 1 @ 40-46; col. 5 @ 34-39; col. 6 @ 20-30).

Modified Sheldon et al. disclose the claimed invention except the therapy shifting the fluid back to the thorax.

Hudrlik discloses an implantable stimulation device to manage fluid flow and teaches that gross tissue insults, created by a significant reduction of blood flow to tissue of the thorax, cause dramatic shifts in the impedance (col. 2 @ 32-35). These fluid shifts are treated by increased pacing rates (col. 11 @ 30-43) for the purpose of assisting in shifting the fluid back to the thorax (col. 2 @ 32-29). Hudrlik teaches impedance and activity monitors are used to define the pacing treatment in situations of fluid shifts (col. 3 @ 9-15). As discussed previously, hypotension is recognized as being associated with a fluid shift to the extremities causing fainting or the feeling of being faint. The fluid shift associated with hypotension is read a significant reduction of blood flow in the thorax. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used thoracic impedance and activity sensors to monitor fluid shifts and to increase the pacing rate as needed to shift fluid back to the thorax in the modified Sheldon et al. system in order to utilize proven monitoring and treatment system for fluid shifts so adequate fluid flow is provided to the thoracic tissue avoiding tissue damage (ischemia) and preventing patient injury from falls that might result if the patient faints (col. 2 @ 32-39).

***Statutory Basis***

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist, telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

FPO
2/21/04

Angela D. Sykes

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